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FILING DATE APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 39/699,765 10/30/00 LATTMANN R 4-20918B/N1 **EXAMINER** 001095 HM12/1011 THOMAS HOXIE MORRIS, P NOVARTIS CORPORATION ART UNIT PAPER NUMBER PATENT AND TRADEMARK DEPT 564 MORRIS AVENUE 1625 SUMMIT NJ 07901-1027 DATE MAILED: 10/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

	Application No.	Appligant(s)
Office Action Summary	07/644.765	Lattmann et al
	Examiner	Group Art Unit
—The MAILING DATE of this communication app	ears on the cover shee	t beneath the correspondence address—
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET OF THIS COMMUNICATION.	TO EXPIRE One	MONTH(S) FROM THE MAILING DATE
 Extensions of time may be available under the provisions of 37 CF from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a If NO period for reply is specified above, such period shall, by defa Failure to reply within the set or extended period for reply will, by st 	a reply within the statutory mi ult, expire SIX (6) MONTHS	nimum of thirty (30) days will be considered timely. from the mailing date of this communication .
Status		
☐ Responsive to communication(s) filed on		
☐ This action is FINAL .		
 Since this application is in condition for allowance exce accordance with the practice under Ex parte Quayle, 1 		
Disposition of Claims		
Claim(s) 1-1)		is/are pending in the application.
Of the above claim(s)		is/are withdrawn from consideration.
☐ Claim(s)		is/are allowed.
☐ Claim(s)	- 1	is/are rejected.
☐ Claim(s)		is/are objected to.
Claim(s)		are subject to restriction or election requirement.
Application Papers		·
 See the attached Notice of Draftsperson's Patent Drave 		
☐ The proposed drawing correction, filed on		
☐ The drawing(s) filed on is/are obj ☐ The specification is objected to by the Examiner.	ected to by the Examine	er.
☐ The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119 (a)-(d)	•	
Acknowledgment is made of a claim for foreign priority All Some* None of the CERTIFIED copies received. received in Application No. (Series Code/Serial Num	of the priority documents	s have been
received in this national stage application from the I	•	
*Certified copies not received:		•
Attachment(s)		
☐ Information Disclosure Statement(s), PTO-1449, Pape		☐ Interview Summary, PTO-413
Notice of Reference(s) Cited, PTO-892		□ Notice of Informal Patent Application, PTO-152
Notice of Draftsperson's Patent Drawing Review, PTO-	948	□ Other

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Part of Paper No.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-4 drawn to compositions and multiple uses, classified in class 514, various subclasses.
- II. Claims 5-10, drawn to compounds of formula (II), classified in classes 540, 544,546 and 548, various subclasses.
- III. Claim 11, drawn to multiple uses, classified in class 514, various subclasses.

The inventions are distinct, each from the other because of the following reasons:

These distinct inventions have acquired separate status in the art, will support separate patents, and will require different fields of search for the respective inventions. Accordingly, restriction for examination purposes as indicated is considered proper; 35 U.S.C. 121; 37 CFR 1.141; 37 CFR 1.142.

Inventions I and II are unrelated because they differ in scope. Applicants' own claims and specification demonstrate that the compounds have different utilities.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in materially different processes as evidenced by applicants' own claims and specification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In the event of an election of either Groups I, II or III, applicants are required to elect a single disclosed species representative of the claimed invention since the variations in R¹, R², R³ etc., encompass all heterocyclic rings classified in classes 540, 544, 546 and 548, various subclasses. Each heterocycle represents an independent and patentably distinct invention. The staggering arrangement of possibilities does not permit classification of the claimed subject matter.

Should applicant(s) traverse on the ground that the species inventions identified are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the above identified species inventions to be obvious variants, or clearly admit on the record that this is the case. In either instance, of traverse, if the examiner finds one of the inventions in the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

"A Markush-type claim is directed to "independent and distinct inventions", if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with

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respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s)". <u>In re Weber</u>, 198 USPQ 330, footnote 3.

CFR 1.141 (a) provides that two or more independent and distinct inventions may not be claimed in one application. In one application means in one application, whether or not the misjoinder occurred in one claim or more than one claim. This is consistent with new PCT Rule 13.3.

"13.3 Determination of Unity of Invention Not Affected by Manner of Claiming.

The determination whether a group of inventions is so limked as to form a single general inventive concept shall be made <u>without</u> regard to whether the inventions are claimed in separate claims or as alternatives within a single claim".

Where restriction is going to be exercised is where independent and distinct inventions are presented in one Markush grouping.

A reference to a pyridine here would not be a reference to a pyrimidine. When one writes out the entire compound, as a whole, one arrives at patentably distinct heterocyclic compounds, along the lines indicated in the Groups of the first page of this action. Distinct, independent, heterocyclic nuclei.

If the members are so diverse that they will support separate patents, *i.e.*, a reference for one would not constitute a reference for the other, then restriction is considered proper. MPEP 2173.05(h).

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It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

In the event of an election of Group I or III, applicants are required to elect a <u>single</u> disclosed method of use, i.e., specific disease.

In, <u>In re Weber</u>, 198 USPQ 332, <u>In re Hengehold</u>, 169 USPQ 473, was noted for the proposition that as long as applicants have maintained the right (as they do here) to file the non-elected subject matter in divisional applications, then restriction is proper, as to that point.

Applicant may file the divisional subject matter noted in divisional applications. If applicant wishes a generic expression of the elected invention the claims here need be amended to reflect that election.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This restriction requirement is being written as previous experience has indicated that with Foreign applicants and the inherent time delays, applicants' representative is better able to make an informed, correct, election of the invention applicants would wish to have prosecuted here if applicants are given the opportunity to see the restriction requirement laid out, and given the time to make an informed decision.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

plm

October 9, 2001